SUMMARY OF SAFETY AND EFFECTIVENESS DATA

August 21, 2003

Submitted By: NuMED, Inc. , 2880 Main St., Hopkinton, NY 12965 (Ph) 315-328-4491

Contact Person: Nichelle LaFlesh

Device Name: NuMED Tyshak Mini Pediatric PTV Catheter; 21 CFR 870.1250 – Percutaneous Catheter

Predicate Devices: NuMED Tyshak Mini Pediatric PTV Catheter

Device Description:

The NuMED, Inc. Tyshak Mini Pediatric PTV catheter is a coaxial catheter for use in PTV applications where a small introduction site is necessary. The catheters inner and outer shafts are constructed of polymeric tubing. The catheter features a molded proximal end bifurcate with two distinct luminal passages. The inflation lumen terminates into a distally mounted balloon made of polymeric material. This balloon is of the non-compliant variety. This balloon is designed to insert through the smallest possible introduction sleeve. The distal lumen terminates at the tip of the catheter and will accept the passage of the appropriate guidewire. This lumen has radiopaque platinum marker bands under the balloon shoulders for placement using fluoroscopy. The catheter is blue in color and the balloon material is clear. The catheter balloon diameter is stamped onto the Y connector and the inflation extension is labeled with balloon diameter x balloon length x introducer size x shaft size x usable length x guidewire size and the catheter lot number. The catheter is packaged in a polyethylene loop and is double packed in two heat sealed Tyvek pouches. The Tyshak Mini catheter is available in standard diameters from **3mm** to **10mm.** The lengths available will be **0.8cm – 4cm.** The Guidewire size will be **0.014",** and the shaft size will be **2.5Fr and 3.5Fr.**

Biocompatibility Testing:

The materials used in the NuMED Tyshak Mini Pediatric PTV Catheter are the same as those used in the already approved Tyshak Mini Catheter (510(k) #K003276) which were tested for biocompatibility in compliance with the Tripartite Biocompatibility Guidance for Medical Devices.

Test results indicate that all materials demonstrate the biocompatibility of the NuMED catheter and are on file at NuMED, Inc. Copies are included in this section.

Laboratory (Bench) Testing: All bench testing was performed in accordance with GMP's and the results are kept on file at NuMED, Inc.

Intended Use:

This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve in Pediatric applications.

- A patient with isolated pulmonary stenosis.
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

Comparison Information:

MODEL:	NUMED TYSHAK MINI	NUMED TYSHAK MINI WITH ADDITIONAL SIZES
Indications:	This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve in Pediatric applications. ▪ A patient with isolated pulmonary stenosis. ▪ A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.	This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve in Pediatric applications. ▪ A patient with isolated pulmonary stenosis. ▪ A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.
Introducer:	2.5Fr – 3.5Fr	2.5Fr – 3.5Fr
Shaft Size:	3Fr – 4Fr	3Fr – 4Fr
Guidewire Size:	0.014"	0.014"
Usable Length:	65cm	20cm - 65cm
Balloon Diameter:	4mm – 10mm	3mm – 10mm
Balloon Length:	2cm – 4cm	0.8cm – 4cm
Materials:	Shaft: Pebax Balloon: PES2 Image Band: Platinum	Shaft: Pebax Balloon: PES2 Image Band: Platinum
Construction:	Coaxial construction with distally mounted non-compliant balloons.	Coaxial construction with distally mounted non-compliant balloon.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2003

NuMED, Inc.
c/o Ms. Nichelle R. LaFlesh
Regulatory Affairs Manager
2880 Main Street
Hopkinton, NY 12965

Re: K032591
Trade Name: NuMED, Inc. Tyshak Mini Pediatric PTV Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: August 21, 2003
Received: August 22, 2003

Dear Ms. LaFlesh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

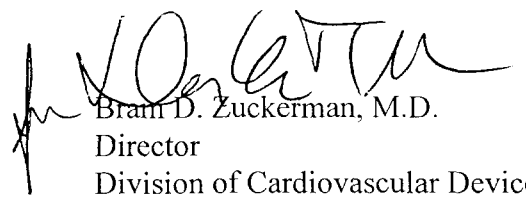
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Brian D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known):

Device Name: **NuMED Tyshak Mini Pediatric PTV Catheter**

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This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve in Pediatric applications.

- A patient with isolated pulmonary stenosis.
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032591

(Optional Format 1-2-96)